

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION**

JEFFREY BOTTOMS,

*Plaintiff,*

vs.

C.R. BARD, INC., a New Jersey corporation,  
& BARD PERIPHERAL VASCULAR, INC.,  
(a subsidiary and/or division of defendant C.R.  
BARD, INC.) an Arizona corporation, and  
DOES 1-10.

*Defendants.*

) Case No. \_\_\_\_\_

) **COMPLAINT FOR DAMAGES**

) **1. NEGLIGENCE**

) **2. STRICT LIABILITY FAILURE TO WARN**

) **3. STRICT LIABILITY DESIGN DEFECT**

) **4. STRICT LIABILITY MANUFACTURING  
DEFECT**

) **5. BREACH OF EXPRESS WARRANTY**

) **6. BREACH OF IMPLIED WARRANTY OF  
MERCHANTABILITY**

) **7. FRAUD AND CONCEALMENT**

) **DEMAND FOR A JURY TRIAL**

Plaintiff, JEFFREY BOTTOMS, by and through his undersigned attorneys, hereby sues  
Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC., and DOES 1-10  
(collectively “Bard”), and alleges as follows:

**PARTIES**

**Plaintiff**

1. Plaintiff JEFFREY BOTTOMS is a resident of Oklahoma. On or about October 13, 2013,  
Plaintiff underwent placement of a Bard Meridian Filter at Memorial Hermann Southeast Hospital in  
Houston, Texas. On or about February 13, 2020, Mr. Bottoms underwent a CT scan which revealed that  
the Meridian Filter had fragmented into multiple pieces, those pieces had migrated throughout his body,  
including into his heart. The fragmented device cannot be safely removed and has caused and will  
continue to Plaintiff pain and suffering, loss of ability to enjoy life, and economic loss.

**Defendants**

1           2. Defendant C.R. Bard, Inc. (“Bard”) is a corporation duly organized and existing under  
2 the laws of the state of Delaware and has its principal place of business in New Jersey. Bard at all times  
3 relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled,  
4 processed, marketed, distributed, and sold the Meridian Filter to be implanted in patients such as the  
5 Plaintiff throughout the United States, including Texas, and was authorized to do business in Texas.  
6

7           3. Defendant Bard Peripheral Vascular, Inc. (“BPV”) is a wholly owned subsidiary corporation  
8 of Defendant C.R. Bard, and is a foreign corporation authorized to do business in Texas and said  
9 Defendant was doing business in Harris County, Texas. BPV, at all times relevant to this action,  
10 designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed,  
11 distributed, and sold the Meridian Filter to be implanted in patients such as the Plaintiff throughout the  
12 United States, including Texas.  
13

14           4. The true names and/or capacities, whether individual, corporate, partnership, associate,  
15 governmental, or otherwise, of Defendant DOES 1 through 10, inclusive, are unknown to Plaintiffs at  
16 this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are informed and  
17 believe, and thereon allege, that each Defendant designated herein as a DOE are liable for the injuries  
18 suffered by Plaintiff by virtue of their purchase and/or assumption of the rights and liabilities of Bard  
19 and/or BPV, as well as their assumption of post-market surveillance obligation regarding the Meridian  
20 Filter and failure to conduct a timely recall and/or provide post-sale warnings. Plaintiffs seek leave to  
21 amend this Complaint to allege the true names and capacities of said DOE defendants when the same are  
22 ascertained.  
23  
24

25           5. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned,  
26 each of the Defendants and each of the DOE defendants were the agent, servant, employee and/or joint  
27 venturer of the other co-defendants and other DOE defendants, and each of them, and at all said times  
28

1 each Defendant and each DOE defendant was acting in the full course, scope, and authority of said  
2 agency, service, employment and/or joint venture.

3 6. Plaintiff is informed and believes, and thereon alleges, that at all times mentioned herein,  
4 Defendants and DOES 1 through 10, and each of them, were also known as, formerly known as, and/or  
5 were the successors and/or predecessors in interest/business/product line/or a portion thereof, assigns, a  
6 parent, a subsidiary (wholly or partially owned by, or the whole or partial owner), affiliate, partner, co-  
7 venturer, merged company, alter egos, agents, equitable trustees and/or fiduciaries of and/or were  
8 members in an entity or entities engaged in the funding, researching, studying, manufacturing,  
9 fabricating, designing, developing, labeling, assembling, distributing, supplying, leasing, buying,  
10 offering for sale, selling, inspecting, servicing, contracting others for marketing, warranting, rebranding,  
11 manufacturing for others, packaging, and advertising the Device. Defendants and DOES 1 through 10,  
12 and each of them, are liable for the acts, omissions and tortious conduct of its successors and/or  
13 predecessors in interest/business/product line/or a portion thereof, assigns, parent, subsidiary, affiliate,  
14 partner, co-venturer, merged company, alter ego, agent, equitable trustee, fiduciary and/or its alternate  
15 entities in that Defendants and DOES 1 through 10, and each of them, enjoy the goodwill originally  
16 attached to each such alternate entity, acquired the assets or product line (or a portion thereof), and in  
17 that there has been a virtual destruction of Plaintiff's remedy against each such alternate entity, and that  
18 each such Defendant has the ability to assume the risk-spreading role of each such alternate entity.  
19

20 7. All references to "Bard" or "Defendants" hereafter shall refer to Defendants Bard, BPV and  
21 DOES 1-10.

### 22 **JURISDICTION AND VENUE**

23 8. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a) (1) because the Plaintiff and  
24 the Defendants are citizens of different states, and the amount in controversy exceeds seventy-five  
25 thousand dollars (\$75,000.00), excluding interest and costs.  
26

27 9. Venue is proper in this Court, as the facts and circumstances leading to injuries occurred  
28 in Harris County, Texas. Defendants sold the defective Meridian Filter in Harris County, Texas, and

1 Plaintiff was implanted with the device in Harris County, Texas. Furthermore, the Defendant's herein  
2 were authorized to conduct business in the State of Texas and did conduct business in Harris County,  
3 Texas.

## 4 5 **GENERAL FACTUAL ALLEGATIONS**

### 6 **A. INFERIOR VENA CAVA FILTERS GENERALLY**

7  
8 10. Inferior vena cava ("IVC") filters first came onto the market in the  
9 1960's. Over the years, medical device manufacturers have introduced several different designs of IVC  
10 filters.

11 11. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi")  
12 that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be  
13 implanted, either permanently or temporarily, in the human body, more specifically, within the inferior  
14 vena cava.  
15

16 12. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the  
17 body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis,  
18 through the vena cava and into the lungs. Often times, these thrombi develop in the deep leg veins.  
19 These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are  
20 considered "pulmonary emboli" or "PE". Pulmonary emboli present significant risks to human health.  
21

22 13. These devices have only been cleared by the FDA to prevent recurrent pulmonary embolism  
23 where anticoagulants are contraindicated or have failed. Thus, any use in a patient without a history of  
24 pulmonary embolism, is an off-label use.  
25

26 14. Of note, Bard's internal documents as well as recent medical literature establish that there is  
27 no proven benefit to these devices.  
28

1 15. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For  
2 example, a doctor may prescribe anticoagulation medications such as Heparin, Warfarin, or Lovenox to  
3 regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who are not  
4 candidates for anticoagulation medications may require the permanent or temporary implantation of an  
5 IVC filter to prevent thromboembolic events.  
6

7 16. As indicated above, IVC filters have been on the market for decades. The first  
8 IVC filters marketed were permanent filters. These devices were designed to be implanted into the IVC  
9 permanently. These permanent filters have long-term follow-up data (of up to 20 years and longer)  
10 regarding their use. Beginning in 2003, manufacturers also began marketing what are known as optional  
11 or retrievable filters. These filters are marketed as being designed to be left in permanently or having the  
12 option to retrieve once the risk of pulmonary embolism has passed.  
13

14 **B. THE RECOVERY FILTER®**

15 **i. Simon Nitinol Filter and Bard's Reasoning For Retrievable Filters**

16 17. Bard has distributed and marketed the Simon Nitinol Filter in the United States since 1992.  
18 The Simon Nitinol Filter is a permanent IVC filter, which is substantially safer than Bard's optional  
19 filters and is still sold by Bard today. Bard modified the design of the Simon Nitinol Filter in order to  
20 make a device that was supposed to be equally safe to leave in permanently and/or could be retrieved  
21 once the risk of pulmonary embolism had passed. The modified device was ultimately marketed as the  
22 Recovery® Filter System ("Recovery Filter").  
23

24 18. Bard's stated purpose in designing the Recovery Filter was to increase the overall size of the  
25 market for these devices through off-label promotion and to increase Bard's percentage of that market.  
26 Specifically, Bard marketed the device for patients that were at risk for DVT and PE but that had not  
27  
28

1 actually ever had a pulmonary embolism as required by the FDA label. These included patients who  
 2 were immobilized for periods of time, e.g, orthopedic patients; bariatric patients, and cancer patients.

3 19. Of note, prior to the Recovery filter being cleared for use by the FDA, Bard was losing  
 4 market share in an IVC Filter market that was reported to be worth \$100,000,000 in sales. In July 2001,  
 5 Bard's overall market share was 16-17%. By March 2003, Bard's market share was down to 11-12%.

7 20. Bard's marketing Manager explained Bard's marketing plan for the Recovery Filter in a  
 8 March 28, 2003 Market Appraisal Memorandum. She wrote , "Users can be swayed by ease of use, low  
 9 profile and aggressive marketing even in the absence of solid clinical history and in spite of negative  
 10 clinical experience."

## 12 **ii. FDA Clearance**

13 21. In 2002, Bard and BPV submitted a notification to market the Recovery Filter System for the  
 14 prevention of recurrent pulmonary embolism by placement in the inferior vena cava.<sup>1</sup> On November 27,  
 15 2002, the FDA cleared the device for sale and use in the prevention of recurrent pulmonary embolism  
 16 via *permanent* placement in the vena cava.

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21 <sup>1</sup> Bard and BPV submitted the notification under Section 510(k) of the United States Food, Drug and  
 22 Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq*). The 510(k) review process requires any entity  
 23 engaged in the design, manufacture, distribution or marketing of a device intended for human use to  
 24 notify the FDA 90 days before it intends to market the device and to establish that the device is  
 25 substantially equivalent to a legally marketed predicate device. (21 C.F.R. §§ 807.81, 807.92(a)(3)).  
 26 Substantial equivalence means that the new device has the same intended use and technological  
 27 characteristics as the predicate device. This approval process allows a manufacturer to bypass the  
 28 rigorous safety scrutiny required by the pre-market approval process.

1           22. In April 2003, Bard submitted a notification of intent to market and sell the Recovery Filter  
2 for the additional intended use of *optional retrieval* and Bard received FDA clearance to begin  
3 marketing the Recovery Filter as both a permanent and retrievable filter on or about July 25, 2003.  
4

5           23. Kay Fuller, the ex-BPV employee responsible for submitting materials to the FDA regarding  
6 Defendants application to market the Recovery Filter has testified that she raised safety concerns  
7 regarding the device prior to FDA clearance her bosses at BPV. She further testifies that her concerns  
8 were ignored and that she was threatened with retaliation if she did not drop those safety concerns. She  
9 further testified that Rob Carr, project manager for the Recovery Filter at BPV, created a culture that  
10 was all about rushing the product to market and would not tolerate anything that could slow that process  
11 down. Ms. Fuller quit her job when her safety concerns were ignored. Defendants then forged her  
12 signature on the FDA application to market the device, in order to get it cleared for marketing.  
13

14           24. Ultimately, Bard's plan to promote its retrievable devices for off-label uses and for unproven  
15 benefits succeeded. By 2009, the overall market share for IVC filters had tripled; moreover, Bard's  
16 percentage of that market share has increased from 11-12% to 42%.  
17

18           25. Bard's marketing claims made to all physicians, included, that the Recovery Filter was safer  
19 than all previously available filters, including the Simon Nitinol Filter. As will be discussed below, this  
20 claim was false.  
21

### 22                   **iii. The Design Recovery Filter**

23           26. The Recovery Filter is conical in shape and it consists of two (2) levels of six (6) radially  
24 distributed NITINOL struts that are designed to anchor the filter into the inferior vena cava and to catch  
25 any embolizing clots. There are six short struts, which are commonly referred to as the arms, and six  
26 long struts, which are commonly referred to as the legs. Each strut is held together by a single  
27 connection to a cap located at the top/apex of the device. According to the Patent filed for this device,  
28

1 the short struts are primarily for “centering” or “positioning” within the vena cava, and the long struts  
2 with attached hooks are designed to primarily prevent the device from migrating from “normal  
3 respiratory movement” or even massive pulmonary emboli.

4  
5 27. The Recovery filter is inserted percutaneously by a deployment catheter that is guided by a  
6 physician through a blood vessel into the inferior vena cava. The Recovery Filter is designed to be  
7 retrieved in a similar fashion.

8 28. The Recovery Filter included several design changes from the Simon Nitinol Filter. These  
9 include, but are not limited to, the following:

- 10  
11 a. decreasing the leg span of the device;  
12 b. decreasing the hook diameter of each hook on the leg struts;  
13 c. decreasing the radial force of the struts; and  
14 d. changing the closed petal arm strut design to an open arm strut design.

15  
16 **iv. Bard’s Design Efforts Were Inadequate**

17 29. Each of the design changes referenced above had the unintended consequence of  
18 substantially reducing the Recovery Filter’s stability, i.e. tendency to move whether it being tilting or  
19 migration completely out of the area of placement, and structural integrity and increasing its propensity to  
20 perforate the vena cava.

21  
22 30. However, because Bard failed to conduct adequate testing and research to understand the  
23 anatomy of where the device would be placed and what forces it would be exposed to when used in a  
24 reasonably foreseeable manner, Defendants failed to realize that these design changes would result in  
25 the device not being reasonably safe for user needs.

26  
27 31. In a 2009 Bard IVC Filter franchise review, Bard’s Filter Franchise Team admits that Bard’s  
28 weakness have been a:

- a. Lack of thorough understanding dynamics of caval anatomy – impacting testing methods;
- b. We have a historical reactive/evolution design mindset;
- c. Product complications – forcing focus on reactive designing;
- d. Limited understanding of user needs.

32. Due to Bard's lack of understanding of caval anatomy and the forces the device would be exposed to once implanted, Bard set design specifications that were not clinically relevant and did not account for the forces these devices would actually see when implanted in the human body. For instance, Bard's decision to set the minimum safety standard regarding migration resistance at 50 mmHg reflected a complete lack of understanding of the forces this device could be exposed to once implanted.

33. Bard also failed to test the device under reasonably foreseeable conditions that the device could be exposed to when used in an intended and expected manner. Among other things, Bard knew that these devices could be placed in appropriately sized vena cava that subsequently expanded beyond 28 mm in diameter. Bard knew that this decreased migration resistance if the device was challenged by a clot and could lead to migration if the vena cava expanded beyond the leg span of the filter, such that the hooks were no longer in touch with the vena cava walls. Yet Bard chose not to test the device to simulate how it would perform if caval distension were to occur. Bard also failed to test the device to determine how it would perform if tilted, fractured, or perforating the vena cava in respect to stability and structural integrity.

#### **v. Pre-Market Expectations**

34. Prior to introducing the Recovery Filter and later the G2 and Eclipse Filters to market, Bard and consumer expected that a properly placed filter would remain stable, maintain structural integrity and would not perforate through the vena cava when used in a reasonably foreseeable manner. Bard's internal documents repeatedly support this point:

- a. Bard filed patents for its retrievable filters, which state "An elastic hook is formed on the free end of an appendage to pierce the vessel wall and insure that the filter does not migrate in response to normal respiratory functions or in the event of a massive pulmonary embolism."
- b. Bard's Product Performance Specifications for its retrievable filters provide specifications that are to ensure the following "user needs", that the devices must not migrate, fracture or perforate the vena cava.
- c. Bard's premarket testing, which failed to account for real world conditions, predicated that there would be no fractures, migration, or perforation failures.
- d. Bard's pre-market design and testing documents state that if a clot challenges a filter "pressure below the filter increases significantly and tends to drive the filter toward the heart" and that "the device must not migrate in response to such a challenge."
- e. In a June 2004 Health Hazard Evaluation, Bard's Medical Director states that clot induced migrations are a malfunction of the device and a failure to carry out its intended function.
- f. Bard's own quality engineers working on the retrievable filter projects admit that if one of its filters is driven into the heart by a clot challenge, then the device failed to perform as intended.
- g. In 2004, Bard conducted a physician focus group regarding what were the expected complications from IVC filters. The physicians reported that an IVC Filter must not migrate no matter how big a clot is.
- h. Bard also marketed its retrievable filters as being "self-centering" meaning that they would not tilt in the vena cava.

35. Bard and physicians further expected that Bard's retrievable filters would perform at least as safely and effectively as Bard's permanent filter. For example:

- a. BPV's Vice-President of Quality Assurance, Doug Uelmen and C.R. Bard, Inc.'s Medical director, Dr. Ciavarella, both admit that a device that fails to perform as safely and effectively as a predicate device is adulterated and misbranded under federal law and company must stop selling it.
- b. Bard marketed the Recovery, G2, and the Eclipse Filter as being substantially safer than all previous IVC filters, including the Simon Nitinol Filter.
- c. In 2004, Bard conducted a physician focus group regarding what were the expected complications from IVC filters. The physicians reported that "A retrievable filter is expected to perform just as well as a permanent filter."

**vi. Bard's Post-Market Surveillance Revealed Recovery Filter Did Not Perform as Expected.**

36. Once the Recovery Filter was released to market, Bard became aware from reported complaints, its own investigations and epidemiological studies that the design changes made from the Simon Nitinol Filter to its Recovery Filter had the unintended result of substantially reducing the stability, structural integrity, and perforation resistance of the device.

37. Thus, even when properly placed, the Recovery Filter would move, fracture, and or perforate the vena cava when exposed to normal and expected in vivo forces.

38. These failures often caused severe patient injuries such as:

- i. death;
- ii. hemorrhage;
- iii. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);
- iv. cardiac arrhythmia and other symptoms similar to myocardial infarction;
- v. severe and persistent pain;

vi. and perforations of tissue, vessels and organs.

39. Moreover, Bard was aware that these failures and resulting injuries were far more likely to occur with the Recovery Filter versus other available IVC Filters. For instance:

- a. Multiple studies have reported Bard's Recovery Filter to have a fracture and migration rate ranging from 21% to 31.7%.
- b. In February 2004, Bard's Marketing Manager, Janet Hudnall, sent an email admitting that the Recovery Filter is being reported to have tilted at significantly high rate even though it was initially properly placed. She further requested that this high rate of failure be downplayed to consumers.
- c. In June 2004, Bard's divisional head of Quality Assurance, Doug Uelmen, admitted: "Bard has been in the permanent filter market for 10 years (SNF). We have had a great deal of experience with a traditional patient base, experiencing a very low and unremarkable adverse event rate. We have now moved into the optional filter market with RNF and have experienced increased failures."
- d. By July 2004, Bard's own was aware that the Recovery Filter has a reported fracture rate that was 28 times higher than all other available IVC Filters.
- e. In December 2004, Bard performed a risk assessment of the Recovery Filter, which analyzed reported failure rates, and concluded: "Reports of death, filter migration (movement), IVC perforation, and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 higher, respectively, than reporting rate for all other filters. These differences were all statistically significant, Recovery's reporting rates for all adverse events, filter fracture, filter migration, and filter migration deaths were found to be significantly higher than those for other removable filters." Dr. Ciavarella, Bard's

1 Medical Director, concluded that this risk (substantially higher reported failure rates) was not  
2 known or obvious to consumers, and that Bard should consider providing a warning regarding  
3 the increased reporting rate.

- 4  
5 f. By December 2004, BPV's Vice President of Quality Assurance, Doug Uelmen, admits that  
6 according to Bard's own policy and procedure for when devices should be recalled, the  
7 Recovery filter was considered unreasonably dangerous for human health and required product  
8 correction.

9  
10 40. These failures are attributable, in part, to the fact that the Recovery Filter was designed so as  
11 to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

12 41. In addition to design defects, the Recovery Filter suffers from manufacturing defects. These  
13 manufacturing defects include, but are not limited to, the absence of electropolishing and the existence  
14 of "draw markings" and circumferential grinding markings on the exterior of the surface of the device.  
15 The presence of these draw markings and/or circumferential grinding markings further compromises the  
16 structural integrity of the device while *in vivo*. In particular, the Recovery Filter is prone to fail at or near  
17 the location of draw markings/circumferential grinding markings on the struts of the device. Put simply,  
18 the Recovery Filter is not of sufficient strength to withstand normal placement within the human body.  
19 The presence of the aforementioned exterior manufacturing defects makes the device more susceptible  
20 to failure.  
21  
22

23 **vii. Bard's Design Review Regarding Migration Failures**

24 42. In late 2003, as migrations failures for the Recovery Filter continued to mount, Bard convened a  
25 group to reexamine the adequacy of the design of the Recovery Filter as it relates to its ability to remain stable  
26 after implantation. The group established a number of action items, including the following: an investigation  
27 into what the minimum migration resistance specification of 50 mmHg had been based on, testing comparing  
28

1 the migration resistance of the Recovery Filter to other available filters, and testing comparing radial force  
2 difference between the range of available devices.

3 43. This design review revealed that the minimum safety migration resistance specification was  
4 unsupported and had been set artificially low. Bard developed this critical safety standard based on  
5 undocumented informal estimates obtained from unidentified physicians regarding the highest pressure below a  
6 filter that could be seen in the vena cava (35 mmHg). Bard then tested the device in three (3) sheep and claimed  
7 that the test results confirmed that that 35 mmHg was the highest pressure that could ever be seen in the vena  
8 cava under worst case conditions. Bard then added a safety factor of 15 mmHg, and concluded that its filters  
9 would never migrate. However, the test results from the sheep testing actually show pressure levels well above  
10 50 mmHg.  
11

12 44. Further, Bard's own investigations concluded that multiple properly placed Recovery Filters  
13 migrated and caused death because the filters lacked adequate strength to resist clot challenges and/or lacked an  
14 adequate margin of safety to accommodate post-placement distention of the vena cava. Thus, further  
15 confirming that the safety specification of 50 mmHg was inadequate and that its testing, which predicted no  
16 migration failures, did not accurately reflect real world conditions.  
17

18 45. As part of its design review in early 2004, Bard also spoke with its two long time physician  
19 consultants, Drs. Venbrux and Kaufman. They warned Bard that their input on the migration resistance  
20 specification had just be an "estimate" and that Bard needed to consider revising the migration resistance  
21 specification from 50 mmHg to 140 mmHg. They further warned Bard that the Recovery Filter was a  
22 "wimpy" filter and its radial force also needed to be increased to ensure stability.  
23

24 46. The design review also revealed that the Recovery Filter had migration resistance values that were  
25 far below most other filters, including the Simon Nitinol Filter. Bard's internal records reveal that this was a  
26 known contributing factor to why Bard anchoring mechanism was insufficient to assure stability.  
27  
28

1           47. Bard knew that caval distension (expansion of the vena cava diameter beyond the size at  
2 placement) could occur from multiple factors. These factors included: anesthesia, hydration following medical  
3 procedure such as bariatric procedures, exertion from exercise, coughing, straining during bowel movements.  
4 However, Bard to date has failed to make any efforts to determine the size of vena cava distension that can  
5 occur.  
6

7                           **viii. Bard's Investigation Regarding Fractures**

8           48. In 2004, Bard also investigated what was causing the Recovery Filter to fracture. Among  
9 other things, Bard believed that movement, whether it be tilting or migration of more than 2 cm,  
10 substantially increased the risk of fracture. Bard also determined that perforation of struts through the  
11 wall of the vena cava was causing fractures. Bard also discovered that tilt also led to the inability to  
12 retrieve the device and/or could lead to fractures during retrievals. Bard was also aware of other factors  
13 causing fractures:  
14

- 15                   a.       On June 18, 2003, BPV engineer, Robert Carr, sent an email noting that  
16                           chamfering the edge of cap would reduce the likelihood of fracture;
- 17                   b.       On March 16, 2004, a BPV engineer sent an email admitting that the surface  
18                           damage, as seen on the Recovery® Filter from the manufacturing process,  
19                           decreases fatigue resistance and that electropolishing increases fatigue resistance;
- 20                   c.       On May 5, 2004, a BPV engineer sent an email stating that adding a “chamfer” to  
21                           filter will “address the arm fracture issue.”
- 22                   d.       On May 26, 2004, a BPV engineer sent an email stating that a proposed modified  
23                           Recovery® Filter design with a large chamfer lasted 50 bending cycles before  
24                           breaking, whereas another proposed modified Recovery® Filter with a small  
25                           chamfer broke after 10 bending cycles.  
26

27                           **ix. Bard Conducts Silent Recall of Recovery Filter**  
28

1           49. In or around April 2004 Bard, without notifying consumers of the design and manufacturing  
2 flaws inherent in the Recovery Filter, began redesigning the Recovery Filter in an attempt to correct its  
3 design flaws. The redesigned filter is known as the G2 Filter, which stands for second generation  
4 Recovery Filter. Once Bard began marketing and selling the redesigned product in approximately  
5 August 2005, Bard quietly stopped selling the Recovery Filter. Of note, however, Bard continued to  
6 market the Recovery Filter as being safer and more effective than all prior filters up until the day the  
7 Recovery Filter was removed from the market. Moreover, Bard never issued a recall for the Recovery  
8 Filter, which had a three (3) year shelf-life.  
9

### 10           **C. THE G2® FILTER SYSTEM**

11           50. On August 29, 2005, Bard obtained clearance to market the G2 Filter through the 510k  
12 process by having represented to the FDA that the G2 Filter was substantially equivalent in respect to  
13 safety and efficacy as the Recovery Filter.  
14

15           51. Bard represented that the differences between the Recovery Filter and the G2 Filter were  
16 primarily dimensional and no material changes or additional components were added. The G2 Filter  
17 was only cleared for permanent implantation until January 15, 2008. Thus, between September 2005  
18 through all of 2007, Bard sold two filters, the Simon Nitinol Filter and G2 Filter, with the exact same  
19 indications for use.  
20

21           52. Bard marketed the G2 Filter as having “enhanced fracture resistance,” “improved centering,”  
22 and “increased migration resistance” over all of its previous filters. Bard’s marketing brochure states  
23 that supporting data was “on file.” Yet, Bard refused to share this allegedly supporting evidence with  
24 consumers when it was asked for it. In reality, Bard knew these claims were false and misleading. Bard  
25 knew that the Simon Nitinol Filter was far less likely to fracture, migrate, tilt, or perforate the vena cava.  
26  
27  
28

1 53. Further, Bard again failed to conduct adequate testing for long term safety and efficacy and  
2 failed to conduct adequate bench testing and animal studies, to ensure that the device would perform  
3 safely and effectively once implanted in the human body and subjected to reasonably foreseeable *in vivo*  
4 stresses. Furthermore, Bard still did not have a thorough and/or adequate understanding of vena caval  
5 dynamics. Not surprisingly, the G2 Filter's design still lacked adequate structural integrity, stability and  
6 perforation resistance to withstand normal *in vivo* body stresses within the human without failing.  
7

8 54. For instance, the new minimum safety migration resistance design requirement for the G2 Filter  
9 was that its migration resistance had to be "statistically greater" than of the predicate Simon Nitinol Filter.  
10 Bard's testing established that the G2 Filter failed this requirement. However, instead of going back and  
11 modifying the device further to ensure this safety requirement was met, Bard changed the minimum safety  
12 requirement to be that it just had to be better than the Recovery Filter, which was the device it was removing  
13 from the market because it migrated when challenged by large clots.  
14

15 55. Compounding this utter lack of concern for patient safety, Bard also decided that G2 filters could  
16 be reworked or reloaded on the jig used to form the filters up to five times in order to save money despite  
17 knowing that this would significantly decrease the migrations resistance of such devices. To allow for this,  
18 Bard readopted the same minimum safety migration resistance specification that had been adopted and proven  
19 to be utterly unsupported for the Recovery Filter, e.g. 50 mmHg.  
20

21 56. Thus, knowing that the specification and migration resistance of the Recovery Filter had been  
22 inadequate and was resulting in patient death, Bard's premarket design requirements was the device had to be  
23 at least as good as the Simon Nitinol Filter regarding migration resistance. When the G2 Filter failed that  
24 requirement, Bard simply changed the design requirement to the G2 Filter just having to be at least as good as  
25 the device that was known to be inadequate and causing patient death.  
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1           57. The Redesigned G2 Filter also still had substantially less radial force than did the Simon  
2 Nitinol Filter.

3           58. Bard also again failed to account for how movement (tilt/migration), perforation, and fracture  
4 would affect device performance despite knowing that these failures had occurred with the Recovery  
5 Filter.  
6

7           59. Also, like its predecessor, in addition to design defects, the G2 Filter suffers from  
8 manufacturing defects. These manufacturing defects include, but are not limited to, the absence of  
9 electropolishing and the existence of “draw markings” and circumferential grinding markings on the  
10 exterior of the surface of the device. The presence of these draw markings and/or circumferential  
11 grinding markings further compromises the structural integrity of the G2 Filter while *in vivo*. In  
12 particular, the G2 Filter is prone to fail at or near the location of draw markings/circumferential grinding  
13 markings on the struts of the device. Put simply, the G2 Filter is not of sufficient strength to withstand  
14 normal placement within the human body. The presence of the aforementioned exterior manufacturing  
15 defects makes the device more susceptible to fatigue failure and migration.  
16  
17

18           60. Within months of being released to market post-market safety data revealed to Bard that the  
19 safety problems introduced with the Recovery Filter had not been corrected. Some representative  
20 examples of this knowledge include the following:  
21

- 22           a. Bard again received large numbers of adverse event reports reporting that properly placed  
23 G2 Filter were, *inter alia*, fracturing, migrating, tilting, and perforating the vena cava  
24 often resulting in serious injuries and death.  
25           b. By November 2005, Bard was aware of a “safety signal” regarding the high rate of  
26 reported perforation and movement failures.  
27  
28

- 1 c. In a December 25, 2005 email, Bard's Medical Director, Dr. David Ciavarella,  
2 questioned why Bard was even selling the G2 filter given the numerous reported failures  
3 when the Simon Nitinol Filter had virtually no reported adverse events.
- 4 d. By no later than February 2006, internal safety investigations revealed that the G2 Filter's  
5 design continued to fail to ensure adequate stability as the device continued to tilt and  
6 migrate at unreasonably high rates. Indeed, within months of being on the market, the G2  
7 filter was found to migrate at rates that violated Bard's own safety threshold. The G2  
8 Filter also exhibited a previously unseen failure mode, in that it would migrate  
9 downwards as well as upwards and side to side in the vena cava.
- 10 e. As with the Recovery Filter, Bard knew that movement, whether it be tilt or migration,  
11 increased the risk fracture and strut perforation through the vena cava as well making the  
12 device irretrievable. For example in a February 2006, Health Hazard Evaluation  
13 regarding G2 Failures, Bard's Medical Director acknowledges that tilt increases the risk  
14 of fracture and perforation and that events can cause serious injury and death. Similarly, a  
15 2009 PowerPoint Presentation prepared by Bard's engineers, movement causes tilt and  
16 that "[T]ilted filter elements are more likely to penetrate IVC and adjacent structures due  
17 to change in the angle between the elements and the IVC." The PowerPoint states that  
18 tilting and perforation or penetration leads to fracture.
- 19 f. Bard's investigations into comparative failure risks between the different available  
20 devices continually showed that the G2 filters posed a substantially higher risk of  
21 migration, tilt, perforation and fracture.
- 22 g. By 2008, physicians were reporting that they believe there were fundamental design  
23 flaws with the G2 filter that was causing it to move, fracture and perforate and requesting  
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1 evidence as to what the reported complication rates were for the device. Bard's corporate  
2 policy was to refuse to disclose such failure rate data.

3 h. In a document dated April 1, 2010, senior Bard employees admit that there were known  
4 quality problems with the G2 line of filters, that Bard's own sales force had lost faith  
5 with the product, and that doctors were refusing to use it do to the numerous reported  
6 failures. The document evidences Bard's plan to reduce the risk of tilting, perforation,  
7 fracture and migration by improving the anchoring system on the G2 line of filters. This  
8 became the Meridian filter, which was cleared through the 510(k) process on October 24,  
9 2011.

10 i. Recent medical studies report that the G2 will suffer a 38 to 40 percent fracture rate at  
11 four to five years.

12 61. As with the Recovery Filter, these failures often cased severe patient injuries such as:

- 13 a. death;  
14 b. hemorrhage;  
15 c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area  
16 around the heart);  
17 d. cardiac arrhythmia and other symptoms similar to myocardial infarction;  
18 e. severe and persistent pain;  
19 f. and perforations of tissue, vessels and organs.

20 62. Despite being aware from February 2006 that the G2 Filer was not safe for its intended use  
21 and was substantially more likely to fail and cause patient injuries than all other available IVC Filters  
22 devices, Bard continued to sell the device into 2010 and even continued to market it as being safer than  
23 Bard's permanent filter, the Simon Nitinol Filter.  
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1           **D. The G2 Express® and Eclipse® Filter**

2           63. On July 30, 2008, Bard obtained clearance to begin marketing the G2 Express® Filter (G2  
3 Express) via the 510k process. The filter is the identical in design to the G2 Filter except that it has a  
4 hook at the top of the device, which allows it to be retrieved by snares, as well as Bard's Recovery  
5 Cone. The G2 Express Filter contained no design fixes to alleviate the stability, structural integrity and  
6 perforation problems that Bard knew to exist with the G2 Filter.  
7

8           64. On January 14, 2010, Bard obtained clearance to begin marketing the Eclipse® Filter  
9 ("Eclipse Filter") via the 510k process. Bard obtained clearance by representing that the Eclipse Filter  
10 was substantially equivalent to the G2 Express Filter in respect to safety and efficacy and that the only  
11 change "was an improvement of the surface finish of the filter raw material wire by electropolishing the  
12 wire prior to forming the filter." Adding electropolishing to the manufacturing process was intended to  
13 improve structural integrity by removing manufacturing defects caused by the manufacturing process,  
14 which were believed to be increasing the risk of fracture. This device did not incorporate any design  
15 changes to address the known stability, perforation and structural integrity design problems experienced  
16 by the device.  
17

18           65. Both devices continued to experience the unacceptably high failure modes and patient  
19 injuries originally introduced with the design changed in the Recovery Filter.  
20

21           **E. The Meridian® Filter**

22           66. Bard obtained clearance from the FDA to market the Filter in August 2011.  
23

24           67. Bard represented to the FDA that the Meridian Filter was substantially similar to the Eclipse  
25 Filter and could therefore be cleared via the less onerous 510(k) process.  
26

27           68. The stated purpose and expectations for the design modifications made to the Meridian filter  
28 were that the would not migrate, tilt, perforate the vena cava, or fracture.

1           69. However, Bard knew both based on its internal testing, inadequate as it was, as well as well  
2 as early post-market surveillance data that the Meridian Filter continued to suffer from inadequate  
3 design and manufacturing defects causing the device to have unreasonably high tendency to fracture,  
4 migrate, tilt and perforate the vena cava like its earlier generations of optional filters. Therefore, Bard  
5 knew long before Plaintiff was implanted with a Meridian filter, that the Meridian Filter was not  
6 substantially equivalent in safety or performance as the Simon Nitinol Filter, which mean Bard knew the  
7 Meridian Filter was misbranded and adulterated.  
8

9           70. The design of the Meridian Filter is based on the Eclipse Filter, which in turn, is based  
10 entirely on the G2 Filter, which, in turn is base don the Recovery Filter. Like the Eclipse Filter, the wires  
11 used in the Meridian Filter are electropolished prior to the form of the filter. The only added feature to  
12 the Meridian Filter was a caudal anchoring systems added in an attempt to reduce the prevalence of filter  
13 causal migrations toward the groin. Therefore, despite knowing of the high likelihood of perforation  
14 posed by its filter designs and the increased risk of fracture posed by perforation, Bard failed to include  
15 any design change in this product to ameliorate that risk.  
16  
17

#### 18           **F. The Denali® Filter**

19           71. At the same time Bard was working to fix design defects in the G2 Filter in what became the  
20 Meridian Filter, it was also working on the Denali® Filter (“Denali Filter”) as another means to correct  
21 these design flaws. Bard obtained 510k clearance to begin marketing the Denali Filter on April 5, 2013  
22 by claiming it was substantially similar to the Eclipse Filter in respect to safety and efficacy.  
23

24           72. The Denali Filter incorporated design changes to fix design defects in the G2, G2 Express,  
25 Express, and Meridian Filters regarding the devices’ inadequate stability, structural integrity and  
26 propensity to perforate the vena cava. These design changes included, *inter alia*, an improved anchoring  
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28

1 system and “penetration limiters.” The stated purpose and expectations of these design changes is that  
2 the device would not migrate, tilt, perforate the vena cava, or fracture.

3 73. Even after Bard released the Denali Filter, it failed to recall the older generation devices,  
4 including the Meridian, and/or to warn consumers about the increased risk posed by these devices.  
5 Instead, Bard conducted another silent recall. It stopped manufacturing the older device, sold remaining  
6 units, and allowed hospitals to use up units already on their shelves.  
7

8 74. As a result, Plaintiff was implanted with a known defective device, when Bard alleged there  
9 was a safer alternative design available.  
10

11 75. Plaintiff further alleges that Bard acted in willful, wanton, gross and total disregard for the  
12 health and safety of the users or consumers of Eclipse Filter, acted to serve their own financial interests,  
13 and having reason to know and consciously disregarding the substantial risk that their product might kill  
14 or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of  
15 conduct knowing that such conduct created a substantial risk of significant harm to other persons.  
16

#### 17 **G. FDA WARNING LETTER**

18 76. On July 13, 2015, the FDA issued a warning letter notifying Bard that its IVC Filters are  
19 adulterated and misbranded under federal law.

20 77. The FDA noted that the Recovery Cone Removal Systems are adulterated pursuant to  
21 501(f)(1)(B) of 21 U.S.C. § 351(f)(1)(B) and misbranded pursuant to section 21 U.S.C. 352(o) because  
22 these devices have never been cleared or approved for use in humans. Thus, the FDA demanded that  
23 Bard immediately cease commercial distribution of its Recovery Cone Removal Systems.  
24

25 78. The FDA notified Bard that its IVC Filters are adulterated and misbranded because the  
26 methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation  
27 are not in conformity with the current good manufacturing practice requirements of the Quality System  
28

1 regulation found at Title 21, Code of Federal Regulations (CFR), Section 820, and that Bard failed to  
2 comply with adverse event reporting requirements of 21 C.F.R. 803.

3 79. The FDA cites numerous specific violations, including the failure to establish and maintain  
4 procedures to ensure that product complaints are adequately investigated and reported, and a consistent  
5 pattern of Bard underreporting the severity of injuries caused by device failures and failing to report  
6 device malfunctions all together. For instance, the FDA cites numerous examples of Bard reporting G2,  
7 and G2 Express and Eclipse Filter failures resulting in death and other serious injuries as if there was no  
8 patient injury involved. Other examples of Bard's failures include the FDA finding Bard failed to  
9 establish and maintain a procedure to ensure that the toxic acids and chemicals used in the manufacture  
10 of its filters were reduced to acceptable levels prior to distribution.  
11

### 12 **SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF**

13 80. On or about October 13, 2013, Plaintiff Jeffrey Bottom underwent placement of a Bard  
14 Meridian Filter at Memorial Hermann Southeast Hospital in Houston, Texas. On or about February 13,  
15 2020, Mr. Bottoms underwent a CT scan which revealed that the Meridian Filter had fragmented into  
16 multiple pieces, those pieces had migrated throughout his body, including into his heart. The fragmented  
17 device cannot be safely removed and has caused and will continue to Plaintiff pain and suffering, loss of  
18 ability to enjoy life, and economic loss.  
19

### 20 **FRAUDULENT CONCEALMENT**

21 81. Any applicable statutes of limitation have been tolled by the knowing and active concealment  
22 and denial of material facts known by Bard when they had a duty to disclose those facts. They have  
23 kept Plaintiff and his physicians ignorant of vital information essential to the pursuit of their claims,  
24 without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's  
25 part in filing on his causes of action. Bard's fraudulent concealment did result in such delay.  
26  
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28

1 82. Bard is estopped from relying on the statute of limitations defense because Bard failed to  
2 timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature  
3 of the Meridian Filter.

4  
5 83. Bard has failed to ever issue a recall for the Meridian Filter, has never admitted is exposed  
6 Plaintiff's to increased risks, that it knew the Meridian Filter had substantially higher reported failure  
7 rates, and/or that it redesigned the device because of design defects that were known to exist as early as  
8 2011.

9  
10 84. Bard was under a continuing duty to disclose the true character, quality and nature of the  
11 device that was implanted in the Plaintiff, but instead they concealed them. Bard's conduct, as  
12 described in this Complaint, amounts to conduct purposely committed, which Bard must have realized  
13 was dangerous, needlessly reckless, without regard to the consequences or the rights and safety of  
14 Plaintiff.

15  
16 **CORPORATE/VICARIOUS LIABILITY**

17 85. At all times herein mentioned, the Bard Defendants were the agents, servants, partners, co-  
18 conspirators and/or joint venturers of each of the other and were at all times operating and acting within  
19 the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture  
20 and rendered substantial assistance and encouragement to the other, knowing that their collective  
21 conduct constituted a breach of duty owed to the Plaintiff.

22  
23 86. There exists and, at all times herein mentioned, there existed a unity of interest in ownership  
24 between the Bard Defendants such that any individuality and separateness between these Bard  
25 Defendants has ceased and these Defendants are the alter ego of the other and exerted control over one  
26 another. Adherence to the fiction of the separate existence of the Bard Defendants as entities distinct  
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28

1 from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would  
2 promote injustice.

3 87. At all times herein mentioned, the Bard Defendants, and each of them, were engaged in the  
4 business of, or were successors in interest to, entities engaged in the business of researching, designing,  
5 formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting,  
6 distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and  
7 selling products for use by the Plaintiff. As such, each Bard Defendant is individually, as well as jointly  
8 and severally, liable to the Plaintiff for Plaintiff's damages.  
9  
10

11 88. At all times herein mentioned, the officers and/or directors of the Bard Defendants named  
12 herein participated in, authorized and/or directed the production and promotion of the aforementioned  
13 products when they knew, or with the exercise of reasonable care and diligence should have known, of  
14 the hazards and dangerous propensities of the Meridian Filter, and thereby actively participated in the  
15 tortious conduct that resulted in the injuries suffered by the Plaintiff.  
16

17 **COUNT I - NEGLIGENCE**

18 89. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the  
19 foregoing paragraphs as though fully set forth herein.  
20

21 90. At all times relevant to this cause of action, the Bard Defendants were in the business of  
22 designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the  
23 Meridian Filters.

24 91. Bard designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold  
25 the Meridian Filter that was implanted in Plaintiff on .  
26  
27  
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1 92. Bard had a duty to exercise reasonable and prudent care in the development, testing, design,  
2 manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Meridian Filter so  
3 as to avoid exposing others to foreseeable and unreasonable risks of harm.

4  
5 93. Bard knew or reasonably should have known that the Meridian Filter was dangerous or was  
6 likely to be dangerous when used in its intended or reasonably foreseeable manner.

7 94. At the time of manufacture and sale of the Meridian Filter, Bard knew or should have known  
8 that the Meridian Filter:

- 9  
10 a. Was designed and manufactured in such a manner so as to present an unreasonable risk  
11 of fracture of portions of the device;  
12 b. Was designed and manufactured so as to present an unreasonable risk of migration of the  
13 device and/or portions of the device; and/or  
14 c. Was designed and manufactured so as to present a unreasonable risk of the device tilting  
15 and/or perforating the vena cava wall and/or could not be removed percutaneously;  
16 d. Was designed and manufactured to have unreasonable and insufficient strength or  
17 structural integrity to withstand normal placement within the human body.  
18

19 95. At the time of manufacture and sale of the Meridian Filter, Bard knew or should have known  
20 that using the Meridian Filter as intended or in a reasonably foreseeable manner created a significant risk  
21 of a patient suffering and severe health side effects including, but not limited to: hemorrhage;  
22 cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction;  
23 perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are  
24 permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and  
25 disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic  
26 injuries/illness proximately caused by the device; and the continued risk of requiring additional medical  
27  
28

1 and surgical procedures including general anesthesia, with attendant risk of life threatening  
2 complications.

3 96. Bard knew or reasonably should have known that consumers of the Meridian Filter would not  
4 realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable  
5 manner.  
6

7 97. Bard breached their to duty to exercise reasonable and prudent care in the development,  
8 testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the  
9 Meridian Filter in, among other ways, the following acts and omissions:  
10

11 a. Designing and distributing a product in which they knew or should have known  
12 that the likelihood and severity of potential harm from the product exceeded the burden  
13 of taking safety measures to reduce or avoid harm;

14 b. Designing and distributing a product in which they knew or should have known  
15 that the likelihood and severity of potential harm from the product exceeded the  
16 likelihood of potential harm from other device available for the same purpose;

17 c. Failing to use reasonable care in manufacturing the product and producing a  
18 product that differed from their design or specifications or from other typical units from  
19 the same production line;  
20

21 d. Failing to use reasonable care to warn or instruct, including pre and post-sale,  
22 Plaintiff, Plaintiff's physicians, or the general health care community about the Meridian  
23 Filter's substantially dangerous condition or about facts making the product likely to be  
24 dangerous;  
25

26 e. Failing to perform reasonable pre and post-market testing of the Meridian Filter to  
27 determine whether or not the product was safe for its intended use;  
28

- f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Meridian Filter;
- g. Advertising, marketing and recommending the use of the Meridian Filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the device;
- h. Representing that the Meridian Filter was safe for its intended use when, in fact, Bard knew and should have known the products were not safe for its intended purpose;
- i. Continuing to manufacture and sell the Meridian Filter with the knowledge that said products were dangerous and not reasonably safe, and failing to comply with good manufacturing regulations;
- j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Meridian Filter so as to avoid the risk of serious harm associated with the use of these filter systems;
- k. Failing to establish an adequate quality assurance program used in the manufacturing of the Meridian Filter.
- l. Failing to establish and maintain an adequate post-market surveillance program;
- m. Failing to remove the Meridian Filter from the market, and
- n. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

98. As a direct and proximate result of the foregoing negligent acts and omissions by the Bard Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device.

1 Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of  
2 life threatening complications and ongoing medical care to monitor the fractured Meridian Filter pieces  
3 that have migrated throughout his body to ensure that it does not cause additional or further injury.  
4

5 **COUNT II - NEGLIGENT FAILURE TO WARN**

6 99. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the  
7 foregoing paragraphs as though fully set forth herein.  
8

9 100. Bard designed, set specifications, manufactured, prepared, compounded, assembled,  
10 processed, marketed, labeled, distributed, and sold the Meridian Filter, including the one implanted into  
11 Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the  
12 devices to consumers or persons responsible for consumers.

13 101. At the time Bard designed, manufactured, prepared, compounded, assembled, processed,  
14 marketed, labeled, distributed, and sold the devices into the stream of commerce, Bard knew or should  
15 have known the Meridian Filter presented an unreasonable danger to users of the product when put to  
16 their intended and reasonably anticipated use. Specifically, Bard knew or should have known at the time  
17 they manufactured, labeled, distributed and sold the Meridian Filter, which was implanted in Plaintiff,  
18 that the Meridian Filter, *inter alia*, posed a significant and higher risk for fracture, migration, tilting,  
19 perforation of the vena cava wall and an inability to remove the filter percutaneously and resulting  
20 serious injuries, including death, than other similar devices, including Bard's own Simon Nitinol Filter.  
21

22 102. Therefore, Bard had a duty to warn about the particular risks of the G2 Filter and to  
23 provide adequate instructions on the safe and proper use of the device. Bard further had a duty to warn  
24 of dangers and proper safety instructions that it became aware of even after the device was distributed  
25 and implanted in the Plaintiff. The Defendant's knew or should have known that the G2 Filter was  
26 dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.  
27  
28

1           103. Despite this duty, Bard failed to adequately warn of material facts regarding the safety  
2 and efficacy of the Meridian Filter, and further failed to adequately provide instructions on the safe and  
3 proper use of the device.

4           104. No health care provider or patient, including Plaintiff and her physicians, would have  
5 used the device in the manner directed, had those facts been made known to the prescribing healthcare  
6 providers and/or ultimate users of the device.

7           105. The health risks associated with the device as described herein are of such a nature that  
8 ordinary consumers would not have readily recognized the potential harm.

9           106. Plaintiff and Plaintiff's health care providers used the Meridian Filter in a normal,  
10 customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent  
11 pulmonary embolisms.

12           107. Therefore, the Meridian Filter implanted in Plaintiff was defective and unreasonably  
13 dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling  
14 and/or instructions accompanying the product.

15           108. The Meridian Filter implanted in Plaintiff was in the same condition as when it was  
16 manufactured, inspected, marketed, labeled, promoted, distributed and sold by Bard.

17           109. As a direct and proximate result of the foregoing negligent acts and omissions by the  
18 Bard Defendants, Plaintiff has suffered and will continue to suffer significant medical expenses, pain  
19 and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the  
20 device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including  
21 risk of life threatening complications and ongoing medical care to monitor the fractured Meridian Filter  
22 strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

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28           **COUNT III - STRICT LIABILITY FAILURE TO WARN**

1           110. Plaintiff re-alleges and incorporates by reference each and every allegation contained in  
2 the forgoing paragraphs as though fully set forth herein.

3           111. Defendants designed, set specifications, manufactured, prepared, compounded,  
4 assembled, processed, marketed, labeled, distributed, and sold the Meridian Filter, including the one  
5 implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and  
6 marketed the device to consumers or persons responsible for consumers.

7  
8           112. At the time Defendants designed, manufactured, prepared, compounded, assembled,  
9 processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants  
10 knew or should have known the device presented an unreasonable danger to users of the product when  
11 put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known  
12 at the time they manufactured, labeled, distributed and sold the Meridian Filter, which was implanted in  
13 Plaintiff, that the Meridian Filter, *inter alia*, posed a significant and higher risk than other similar  
14 devices of device fracture, migration, tilting, and perforation of the vena cava wall and resulting serious  
15 injuries. Bard also knew that there were specific design problems with the Meridian Filter that were  
16 causing it lack sufficient structural integrity and stability and causing it to have a high tendency to  
17 perforate the vena cava, and yet Bard failed to warn the public of these problems. Bard also falsely  
18 marketed the product as being less likely to tilt, fracture, and migrate than its other filters. Finally, Bard  
19 also downplayed the risk of harm by just stating that serious injuries had been reported but failing to  
20 warn that serious injuries, including, death had been confirmed to have resulted from failures of the  
21 Meridian Filter.

22           113. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of  
23 the device and to provide adequate instructions on the safe and proper use of the device. Defendants  
24  
25  
26  
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1 further had a duty to warn of dangers and proper safety instructions that it became aware of even after  
2 the device was distributed and implanted in Plaintiff.

3 114. Despite this duty, Defendants failed to adequately warn of material facts regarding the  
4 safety and efficacy of the Meridian Filter and further failed to adequately provide instructions on the  
5 safe and proper use of the device. Furthermore, the foreseeable risks of harm from the Meridian Filter  
6 could have been reduced or avoided by providing reasonable instructions and/or warnings and the failure  
7 to provide those instructions or warnings makes the Meridian Filter unreasonably dangerous and renders  
8 the device defective.  
9

10 115. No health care provider, including Plaintiff's, or patient would have used the device in  
11 the manner directed, had those facts been made known to the prescribing healthcare providers and/or  
12 ultimate users of the device.  
13

14 116. The health risks associated with the device as described herein are of such a nature that  
15 ordinary consumers would not have readily recognized the potential harm.  
16

17 117. Plaintiff and Plaintiff's health care providers used the device in a normal, customary,  
18 intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary  
19 embolisms.  
20

21 118. Therefore, the Meridian Filter implanted in Plaintiff was defective and unreasonably  
22 dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling  
23 and/or instructions accompanying the product.

24 119. The Meridian Filter implanted in Plaintiff was in the same condition as when it was  
25 manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.  
26

27 120. As a direct and proximate result of Defendants' lack of sufficient warning and/or  
28 instructions, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and

1 suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device.  
2 Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of  
3 life threatening complications and ongoing medical care to monitor the fractured Meridian Filter strut to  
4 ensure that it does not cause additional or further injury, in an amount to be determined at trial.  
5

6 **COUNT IV - STRICT PRODUCTS LIABILITY DESIGN DEFECT**

7 121. Plaintiff re-alleges and incorporates by reference each and every allegation contained in  
8 the forgoing paragraphs as though fully set forth herein.  
9

10 122. At all times relevant to this action, Bard developed, tested, designed, manufactured,  
11 inspected, labeled, promoted, distributed and sold into the stream of commerce the Meridian Filter,  
12 including the one implanted in Plaintiff.

13 123. The Meridian Filter was expected to, and did, reach its intended consumers without  
14 substantial change in the condition in which it was in when it left Bard's possession. In the alternative,  
15 any changes that were made to the Meridian Filter implanted in Plaintiff were reasonably foreseeable to  
16 Bard.  
17

18 124. The Meridian Filter implanted in the Plaintiff was in a condition unreasonably dangerous  
19 and was expected to, and did, reach its intended consumers without substantial change in the condition  
20 in which it was in when it left the Defendant's possession. In the alternative, any changes that were  
21 made to the filter were reasonably foreseeable to the Defendant's.  
22

23 125. The Meridian Filter implanted in the Plaintiff was defective in design because it failed to  
24 perform as safely as an ordinary consumer would expect when used as intended, or when used in a  
25 manner reasonably foreseeable by the Defendant's and/or the risk of danger in the design outweighed  
26 the benefits of the filter.  
27  
28

1           126. Feasible design changes existed at the time it the Meridian filter implanted in Plaintiff  
2 was distributed, that would have rendered substantially less likely to fail and caused the injuries it did in  
3 this case.

4           127. Plaintiff and Plaintiff's health care providers used the Meridian Filter in a manner that  
5 was reasonably foreseeable to Bard.

6           128. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of  
7 reasonable care discovered the devices defective condition or perceived its unreasonable dangers prior to  
8 Plaintiff's implantation with the device.

9           129. As a direct and proximate result of the Meridian Filter's defective design, Plaintiff has  
10 suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish,  
11 loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed  
12 risk of requiring additional medical and surgical procedures, including risk of life threatening  
13 complications and ongoing medical care to monitor the fractured Meridian Filter strut to ensure that it  
14 does not cause additional or further injury, in an amount to be determined at trial.

15                           **COUNT V - STRICT LIABILITY MANUFACTURING DEFECT**

16           130. Plaintiff re-alleges and incorporates by reference each and every allegation contained in  
17 the foregoing paragraphs as though fully set forth herein.

18           131. Bard designed, set specifications, manufactured, prepared, compounded, assembled,  
19 processed, marketed, labeled, distributed, and sold the Meridian Filter that was implanted into Plaintiff.  
20 The Meridian Filter was unreasonably dangerous because of a manufacturing defect in that it was  
21 different from its intended design and failed to perform as safely as the intended design would have  
22 performed.

1           132. The Meridian Filter implanted in Plaintiff was in a condition unreasonably dangerous and  
2 the filter was expected to and did reach the Plaintiff and/or her physicians without substantial change  
3 affecting the filter.

4           133. Plaintiff and Plaintiff's health care providers used the device in a manner that was  
5 reasonably foreseeable to Bard.

6           134. As a result of this condition, the product injured Plaintiff and failed to perform as safely  
7 as an ordinary consumer would expect when used in a reasonably foreseeable manner.

8           135. As a direct and proximate result of the Meridian Filter's manufacturing defect, Plaintiff  
9 has suffered and will continue to suffer significant medical expenses, pain and suffering, mental  
10 anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also  
11 exposed risk of requiring additional medical and surgical procedures, including risk of life threatening  
12 complications and ongoing medical care to monitor the fractured Meridian Filter strut to ensure that it  
13 does not cause additional or further injury, in an amount to be determined at trial.

14           **COUNT VI - BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY**

15           136. Plaintiff re-alleges and incorporates by reference each and every allegation contained in  
16 the foregoing paragraphs as though fully set forth herein.

17           137. At all times relevant to this action, Bard designed, researched, developed, manufactured,  
18 tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of  
19 commerce the Meridian Filter for use as a surgically implanted device used to prevent pulmonary  
20 embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and  
21 labels.

22           138. At the time and place of the sale, distribution, and supply of the Meridian Filter System to  
23 Plaintiff by way of Plaintiff's health care providers and medical facilities, Bard, through sales  
24  
25  
26  
27  
28

1 representatives, consultants, printed materials and other advertising and marketing efforts expressly  
2 represented and warranted that the Meridian Filter System was safe and effective for its intended and  
3 reasonably foreseeable use.

4  
5 139. The Meridian Filter System did not conform to the express representations made by  
6 Defendants through sales representatives, consultants, printed materials, and other advertising and  
7 marketing efforts. The Plaintiff and her physicians relied on these express representations in the  
8 purchase, use and implantation of the Meridian Filter in the Plaintiff.

9  
10 140. Bard knew of the intended and reasonably foreseeable use of the Meridian Filter, at the  
11 time they marketed, sold, and distributed the product for use by Plaintiff, and warranted the product to  
12 be of merchantable quality, and safe and fit for its intended use.

13 141. Bard represented and warranted to the healthcare community, Plaintiff and Plaintiff's  
14 health care providers, that the Meridian Filter was safe and of merchantable quality and fit for the  
15 ordinary purpose for which the product was intended and marketed to be used.

16  
17 142. The representations and warranties made by Bard were false, misleading, and inaccurate  
18 because the Meridian Filter was defective and unreasonably dangerous and the device was not of  
19 merchantable quality when used in its intended and/or reasonably foreseeable manner.

20 143. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and  
21 judgment of Bard as the designers, researchers and manufacturers of the product, as to whether Meridian  
22 Filter was of merchantable quality and safe and fit for its intended use, and also relied on the warranty of  
23 merchantability and fitness for the particular use and purpose for which the Meridian Filter was  
24 manufactured and sold.  
25  
26  
27  
28

1           144. Bard placed the Meridian Filter into the stream of commerce in a defective, unsafe, and  
2 unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without  
3 substantial change in the condition in which the Meridian Filter was manufactured and sold.

4           145. Bard breached their warranty because their Meridian Filter was not fit for its intended use  
5 and purpose.  
6

7           146. As a proximate result of the Bard Defendants breach of their implied warranties, Plaintiff  
8 has suffered and will continue to suffer significant medical expenses, pain and suffering, mental  
9 anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also  
10 exposed risk of requiring additional medical and surgical procedures, including risk of life threatening  
11 complications and ongoing medical care to monitor the fractured Meridian Filter strut to ensure that it  
12 does not cause additional or further injury, in an amount to be determined at trial.  
13

14           **COUNT VII - BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**  
15

16           147. Plaintiff re-alleges and incorporates by reference each and every allegation contained in  
17 the foregoing paragraphs as though fully set forth herein.  
18

19           148. At all times relevant to this action, Defendants designed, researched, developed,  
20 manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the  
21 stream of commerce the Meridian Filter for use as a retrievable surgically implanted device used to  
22 prevent pulmonary embolisms and for uses other than as approved and indicated in the product's  
23 instructions, warnings, and labels.  
24

25           149. At the time and place of the sale, distribution, and supply of the Defendants' Meridian  
26 Filter to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly  
27 represented and warranted, by labeling materials submitted with the product, that the Meridian Filter  
28

1 System was safe and effective for its intended and reasonably foreseeable use, and that it could be easily  
2 retrieved at any time through a simple percutaneous procedure.

3 150. Defendants knew of the intended and reasonably foreseeable use of the Meridian Filter  
4 and the Recovery Cone Removal System, at the time they marketed, sold, and distributed the products  
5 for use by Plaintiff, and impliedly warranted the products to be of merchantable quality, and safe and fit  
6 for its intended use. Defendants impliedly represented and warranted to the healthcare community,  
7 Plaintiff and Plaintiff's health care providers, that the Meridian Filter were of merchantable quality and  
8 fit for their ordinary purposes for which the products were intended and marketed.  
9

10 151. The representations and implied warranties made by Defendants were false, misleading,  
11 and inaccurate because the Meridian Filter and the Recovery Cone Removal System were defective and  
12 unreasonably dangerous, and not of merchantable quality when used in their intended and/or reasonably  
13 foreseeable manner. Specifically, at the time of Plaintiff's purchase of the products from the Defendants,  
14 through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:  
15

- 16
- 17 a. It was designed in such a manner so as to be prone to a statistically high incidence of  
18 failure, including fracture, migration, excessive tilting, and perforation of the inferior  
19 vena cava;
  - 20 b. It was designed in such a manner so as to result in a statistically significant incidence of  
21 injury to the organs and anatomy; and
  - 22 c. It was manufactured in such a manner so that the exterior surface of the Meridian Filter  
23 System was inadequately, improperly and inappropriately prepared and/or finished  
24 causing the device to weaken and fail.

25 152. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and  
26 judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether  
27 Meridian Filter was of merchantable quality and safe and fit for its intended use, and also relied on the  
28 implied warranty of merchantability and fitness for the particular use and purpose for which the  
Meridian Filters were manufactured and sold.

1           153. Defendants placed the Meridian Filters into the stream of commerce in a defective,  
2 unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff  
3 without substantial change in the condition in which the Meridian Filter was manufactured and sold.  
4

5           154. As a proximate result of Defendants breach of their implied warranties, Plaintiff has  
6 suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish,  
7 loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed  
8 risk of requiring additional medical and surgical procedures, including risk of life threatening  
9 complications and ongoing medical care to monitor the fractured Meridian Filter strut to ensure that it  
10 does not cause additional or further injury, in an amount to be determined at trial.  
11

12                           **COUNT XIII - FRAUDLENT CONCEALMENT**  
13

14           155. Plaintiff re-alleges and incorporates by reference each and every allegation contained in  
15 the foregoing paragraphs as though fully set forth herein.  
16

17           156. At all times relevant to this cause, and as detailed *supra*, Defendants fraudulently  
18 concealed material information concerning the Meridian Filter from Plaintiff, Plaintiff's health care  
19 providers, and the general medical community relating to the safety and efficacy of these devices.  
20

21           157. Defendants marketed and labeled the Meridian Filter as if it could be easily and safely  
22 retrieved using the Recovery Cone Removal System. Defendants concealed, however, that they had  
23 never obtained clearance to market the Recovery Cone Removal System from the FDA.  
24

25           158. Defendants marketed the Meridian Filter as being safer and less likely to fracture,  
26 migrate, or tilt than other devices, including the Simon Nitinol Filter. Yet, Defendants concealed that  
27 they were aware of information suggesting that the Meridian Filter was substantially more likely to  
28 fracture, migrate, tilt, or perforate the vena cava and other internal organs and cause injuries, than were  
other available IVC Filters.

161. As a proximate result of Defendants fraudulent concealment, Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, mental anguish, loss of enjoyment of life, and other losses proximately caused by the device. Plaintiff is also exposed risk of requiring additional medical and surgical procedures, including risk of life threatening complications and ongoing medical care to monitor the fractured Meridian Filter strut to ensure that it does not cause additional or further injury, in an amount to be determined at trial.

162. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

163. Plaintiff is entitled to an award of punitive and exemplary damages based upon Bard's intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

164. Bard had knowledge of, and were in possession of evidence demonstrating that, the G2® Filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Bard failed to:

- a. Inform or warn Plaintiff or her health care providers of the dangers;
- b. To establish and maintain an adequate quality and post-market surveillance system; and
- c. Recall the Meridian® Filter from the market

165. Bard acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

166. As a direct, proximate, and legal result of Bard's acts and omissions as described herein, and Plaintiff's implantation with Bard's defective product, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgement against Defendants for:

- A. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; and consequential damages as allowed by law;
- B. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;
- C. Statutory damages where authorized;
- D. Costs of suit;
- E. Reasonable attorney's fees, where authorized;
- F. Prejudgment interest at the highest rate allowed by law;

1 G. Post-judgement interest at the highest rate allowed by law;

2 H. Such other additional and further relief as Plaintiff may be entitled to in law or equity.

3 **DEMAND FOR JURY TRIAL**

4 Plaintiff hereby demands trial by jury on all issues.

5  
6 Dated: February 3, 2022.

Respectfully Submitted,

7  
8 /s/ Ben C. Martin

9 Ben C. Martin (13052400 TX)

Laura J. Baughman (00791846 TX)

10 Martin Baughman, PLLC

3141 Hood Street, Suite 600

11 Dallas, Texas 75219

12 Telephone: (214) 761-6614

Facsimile: (214) 744-7590

13 [bmartin@martinbaughman.com](mailto:bmartin@martinbaughman.com)

14 [lbaughman@martinbaughman.com](mailto:lbaughman@martinbaughman.com)

[eservice@martinbaughman.com](mailto:eservice@martinbaughman.com)

15 BRENES LAW GROUP, P.C.

16 TROY A. BRENES, CSBN: 249776

17 *(Pro Hac Vice petition pending)*

tbrenes@breneslawgroup.com

18 100 Spectrum Center Drive, Ste. 330

Irvine, CA 92618

19 Phone: (949) 397-9360

20 Fax: (949) 607-4192

21 *Attorneys for Plaintiff*